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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORD, VANESSA L

ART UNIT PAPER NUMBER

1645

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/673,054	Applicant(s) ENGEL ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-124 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,13-15,96,97 and 105-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-12,16-28,67-79,94,95,98-103 and 108-124 is/are rejected.
- 7) ☒ Claim(s) 29 and 121 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/3/04&3/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-29, 67-79, 94-103 and 105-121 on July 13, 2004 is acknowledged. Applicant's species election of cationic surfactants and species election of ocytylthioglucoside with traverse filed on November 5, 2004 are acknowledged. Claims 30-66, 80-93 and 104 have been cancelled. Claims 122-124 have been added. Claims 4-5, 13-15, 96-97 and 105-107 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The traversal is on the grounds that restriction requirement is believed to be improper and should be withdrawn because Applicant asserts that a restriction should never be required unless an examination of all members of a Markush group would be a serious burden on the Examiner. Applicant urges that the searches involve groups of surfactants and cell membrane altering compound and that these searches would overlap. Applicant urges that piecemeal examination should be avoided whenever possible. Applicant urges that unity of invention exists for Markush type claims when (a) the compounds share a common utility and (b) the compounds share a substantial structural feature associated with that utility. Applicant urges that in the instant application the Markush group recites non-ionic surfactants, cationic surfactants and mixtures thereof as well as various cell altering compounds. Applicant urges that the compounds share the common utility of solubilizing or emulsifying mixtures. Applicant urges that the cell altering membrane compounds have the common

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utility of disrupting cell membranes and have common structure functionalities such as polar functional groups that related to their ability to interact with cell membranes.

These arguments have been fully considered but are not found to be persuasive for the reasons below:

MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required. MPEP 803.02 states "a Markush-type claim can include independent and distinct inventions". In the instant case, the claimed composition includes membrane altering compounds such as detergents, ammonium salts, polymers, enzymes and antibiotics to name a few. For example, antibiotics are structurally different from ammonium salts or polymers. Each member of the Markush group is structurally different from the other. Although, Applicant has grouped these compounds into a single membrane altering Markush group, the search for one member of the Markush group would not overlap with the search for another member of the Markush group. Likewise, the surfactant Markush group includes non-ionic surfactants as well as cationic surfactants which are structurally distinct, from one another and would not overlap in a search. It should be remembered that MPEP 803.02 states " a Markush group contains independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claims obvious

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with respect to the other members of the Markush group". It should be noted that the requirement for unity of invention under Markush practice includes: (a) a common utility is shared and (b) a substantial structure feature disclosed as being essential to that utility (MPEP 803.02). The members of the claimed membrane altering and surfactant Markush groups may share a common utility, but do not share a substantial structure feature disclosed as being essential to that utility and both elements are required for unity of invention.

To address Applicant comments regarding piece meal examination, these comments have no barring on the restriction requirement and species election that has been set forth in this application since the instant application has not been examined previously. It should be noted that this Office action is the first action on the merits in this application.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Specification

2. The specification is objected to for the following informalities: The location of the American Type Culture Collection (ATCC) should be changed from Rockville, Maryland to Manassas, Virginia. See page 14 of instant specification.

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3. The use of the trademarks has been noted in this application. See, for example, page 17. They should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Claims 67, 99-103, 108, 112, 114-117 and 121 are objected to because they depend from a non-elected invention.

5. Claim 108 is objected to because it depends from a cancelled claim.

6. Claim 78 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 78 does not further limit the kit of according to claim 68. Claim 78 does not recite claim limitations that are required in addition to the claim limitations set forth in claim 68.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9 and 101 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what Applicant intends by the term "substantially". Clarification is requested.

8. Claims 21 and 113 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what Applicant intends by the term "sufficient". Clarification is requested.

9. Claims 29 and 121 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 6-12, 16-28, 67-79, 94-95, 98-103, 108-120 and 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al (*U.S. Patent No. 6,174,704 B1, published January 16, 2001*) in view of Shultz et al (*U.S. 6,242,235 B1, published June 5, 2001*).

Claims 1-3, 6-12, 16-28, 67-79, 94-95, 98-103, 108-120 and 122-124 are drawn to a composition comprising: (a) at least one surfactant having a hydrophilic-lipophilic balance value in the range from about 11 to about 16 and (b) at least one cell membrane altering compound.

Chu et al teach compositions comprising aqueous solutions of alkylglycoside or alkylthioglycoside, particularly (octylthioglycoside) (columns 1-2). Chu et al teach that the octylthioglycoside used in the compositions range from about 0.5 to about 5% w/v (column 2-3). Chu et al teach that the octylthioglycoside can be included in an aqueous solution at about 0.5% (v/w) to about 5% (v/w) (column 3). This meets the claims limitations "...at least 0.4% and less than 1% (w/v)" and "...between 0.4% and 0.6% (w/v)". Chu et al teach that buffers such as TRIS or HEPES can be added to the compositions to maintain a physiological pH of about 7-8 (column 2). Chu et al teach that the buffers can be

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maintained at a pH of 7.5 (column 3, Example II). Chu et al teach that lysozyme (reduces non-specific binding) can be added to the compositions (column 24, Example 4). Chu et al teach that the invention was used to prepare, extract, detect, purify and collect the isolated proteins (see Examples I-V, columns 3-6). Chu et al teach that the protein products are incubated on Nickel charged resins (magnetic) and further purified using spin columns comprising resins (Example V, columns 5-6). Chu et al teach compositions comprising aqueous solutions of octylthioglucoside used for lysing cells in the protein extraction process (columns 1-2) and Chu et al teach that the octylthioglucosides of the invention can release the protein of interest from the cell membrane or cell wall (column 2). Chu et al also teach that octylthioglucosides have been used for membrane solubilization (column 2). Therefore, claim limitations such as "wherein the cell altering compound inhibits phospholipid sensitive Ca^{+2} dependent protein kinase and attacks cell membranes" and "cell membrane compounds alters membrane permeability or disrupts membranes" are taught in the prior art reference.

Chu et al do not teach cationic surfactants comprising ethoxylated amine such as Tomah E-18-15 or Tomah E-18-5.

Shultz et al teach that cationic surfactants such as Tomah E-18-15 or Tomah E-18-5 are used to stabilize protein compositions (see the Abstract). Shultz et al teach that the cationic surfactants of the invention have a hydrophile-lipophile (HLB) index number of about 10 to 17, preferably about 11 to 16 (column 2). Shultz et al teach that cationic surfactants such as Tomah E-18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and

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reaction enzymes (column 8). Shultz et al teach that the cationic surfactants can be added at concentrations ranging from 0.001% up to 1.0% (column 11). In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Thus, term "kit" constitutes an "intended use". Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

It would be *prima facie* obvious at the time the invention was made to add Tomah E -18-15 and/or Tomah E-18-5 to aqueous solutions of Chu et al comprising octylthioglucosides because Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes in solution (see the Abstract and column 8). It would be expected barring evidence to the contrary that a composition comprising octylthioglucosides (cell-altering membrane), Tomah E -18-15 and/or Tomah E-18-5 (cationic surfactant), lysozyme

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(defoaming agent) and HEPES (buffer salt) would be effective in lysing cells to release proteins and stabilizing the proteins in reaction or storage buffers.

11. No claims allowed. Claims 29 and 121 appear to be free of the cited prior art.

Conclusion

12. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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January 19, 2005


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